

United States Court of Appeals for the Federal Circuit

03-1524
(Serial No. 09/597,608)

SOLICITOR
MAY 17 2004
U.S. PATENT & TRADEMARK OFFICE

IN RE JOHN NGAI and DAVID LIN

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Appealed from: United States Patent and Trademark Office,
Board of Patent Appeals and Interferences

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NONPRECEDENTIAL OPINION ISSUED: March 8, 2004
PRECEDENTIAL OPINION ISSUED: May 13, 2004

Before MICHEL, GAJARSA, and LINN, Circuit Judges.

PER CURIAM.

Petitioners John Ngai and David Lin (collectively "Ngai") appeal from the decision by the Board of Patent Appeals and Interferences ("Board") rejecting claim 19 of the petitioner's patent application No. 09/597,608 (the "'608 application") as being anticipated by prior art. Ex parte Ngai, No. 2002-1092 (BPAI 2003); see 35 U.S.C. § 102(b). We find that the Board's decision is supported by substantial evidence and accordingly affirm.

I. BACKGROUND

The study of nucleic acids, including ribonucleic acids ("RNA"), has a wide variety of applications in the field of biological sciences. Unfortunately, oftentimes the amount of RNA that experimenters can extract from the cells can be quite small. Experimenters

must duplicate the material many times over to assemble a quantity sufficient for experimentation. This process is called "amplification." Additionally, some RNA strands may be difficult to detect in cells. A process called "normalization" enhances experimenters' ability to detect the RNA that is expressed at low levels.

Ngai invented a new method for amplifying and normalizing RNA. He submitted the '608 application to patent this invention. The '608 application contained 20 claims. Claims 1-18 are drawn to a method of amplifying RNA. Claim 1 is representative of the method claims 1-18 and reads:

A method for normalizing and amplifying an RNA population comprising the steps of:
copying the message RNA (mRNA) to form first single stranded (ss) cDNA;
converting the first ss-cDNA to first double stranded (ds) cDNA;
linearly amplifying the first ds-cDNA to form first amplified RNA (aRNA);
tagging the 3' end of the first aRNA with a known sequence to form 3' tagged first aRNA;
copying the 3'-tagged first aRNA to form second ss-cDNA; and
normalizing the mRNA or the first aRNA.

Claim 19 is drawn to a kit designed to perform the method recited in Claim 1. Claim 19 reads:

A kit for normalizing and amplifying an RNA population, said kit comprising instructions describing the method of claim 1 and a premeasured portion of a reagent selected from the group consisting of: oligo dT biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers and nucleotides. (emphasis added).

Ngai does not dispute that prior art teaches a kit comprising instructions and a 10X buffer.¹

¹ Ngai also does not dispute that a 10X buffer is a type of buffer mentioned in proposed claim 19.

Proceedings Below

The Examiner allowed claims 1-18 but rejected claims 19 and 20 as unpatentable, under 35 U.S.C. § 102(b) and 35 U.S.C. § 103 respectively. The Board reversed the rejection with respect to claim 20 and affirmed the rejection of claim 19 as anticipated by prior art.

The Board agreed with the Examiner that prior art anticipates claim 19 because it teaches each and every limitation of the claim including instructions and a buffer agent. The Board concluded that the only difference between the prior art and claim 19 is the content of the instructions. Finding that the content of the instructions was not “functionally related” to the kit, the Board concluded that claim 19 should be rejected as anticipated by prior art.

Ngai appealed the Board’s decision to this Court. The only issue presented by this appeal is whether claim 19 should have been allowed. We have jurisdiction under 28 U.S.C. § 1295(a)(4).

II. STANDARD OF REVIEW

Anticipation is a question of fact. In re Schreiber, 128 F.3d 1473, 1477 (Fed. Cir. 1997). We review PTO’s factual findings for substantial evidence. In re Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000).

III. DISCUSSION

Ngai argues that the addition of new printed matter to a known product makes the product patentable. He rests his argument on the fact that claim 19 is limited to kits containing instructions teaching the method described in claim 1. Ngai argues that because prior art does not teach a limitation of “instructions describing the method of

claim 1," combined with an amplification kit, the petitioner's claim cannot be anticipated. Ngai relies on the language of In re Gulack, 703 F.2d 1381 (Fed. Cir. 1983): "[The] [d]ifference between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of the printed matter." Id. at 1385.

The PTO argues that Ngai's claim merely teaches a new use for an existing product. Thus, according to the PTO, Ngai can claim the new use as a method, but he cannot claim the existing product itself. The PTO relies on a different passage of Gulack and argues that in order to qualify under Gulack, the printed matter must be functionally related to the underlying object. "The critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate." Id. at 1386.

The dispute between Ngai and PTO reduces to the question of the proper meaning of Gulack. The PTO has the better argument. In Gulack, the Board rejected a claim directed to a circular band designed for mathematical and educational purposes. The invention consisted of "(1) a band, ring, or set of concentric rings; (2) a plurality of individual digits imprinted on the band or ring at regularly spaced intervals; and (3) an algorithm by which the appropriate digits are developed." Id. at 1387. The rejection was premised upon the fact that a circular band with items printed upon it was well known in the art. See id. at 1384. We reversed, finding that the numbers printed on the band had a functional relationship to the band itself. The Court stated: "[t]he[] digits are related to the band in two ways: (1) the band supports the digits; and (2) there is an endless sequence of digits--each digit residing in a unique position with respect to every

other digit in an endless loop. Thus, the digits exploit the endless nature of the band.” Id. at 1386-87. Although the prior art disclosed a band with printed matter, the Court concluded that the prior art neither “disclose[d] nor suggest[ed] either feature” of Gulack’s invention. Id. at 1387.

This case, however, is dissimilar from Gulack. There the printed matter and the circularity of the band were interrelated, so as to produce a new product useful for “educational and recreational mathematical” purposes. Here, addition of a new set of instructions into a known kit does not interrelate with the kit in the same way as the numbers interrelated with the band. In Gulack, the printed matter would not achieve its educational purposes without the band, and the band without the printed matter would similarly be unable to produce the desired result. Here, the printed matter in no way depends on the kit, and the kit does not depend on the printed matter. All that the printed matter does is teach a new use for an existing product. As the Gulack court pointed out, “[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability.” Id. If we were to adopt Ngai’s position, anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product. This was not envisioned by Gulack. Ngai is entitled to patent his invention of a new RNA extraction method, and the claims covering that invention were properly allowed. He is not, however, entitled to patent a known product by simply attaching a set of instructions to that product.

CONCLUSION

For the foregoing reasons, we find that the Board's decision is supported by substantial evidence, and accordingly affirm.

AFFIRMED

IV. COSTS

No costs.

**BRIEF FOR APPELLEE DIRECTOR OF
THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

Appeal No. 03-1524
(Serial No. 09/597,608)

IN RE JOHN NGAI and DAVID LIN

Appeal from the Board of Patent Appeals and Interferences

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19. A kit for normalizing and amplifying an RNA population, said kit comprising instructions describing the method of claim 1 and a premeasured portion of a reagent selected from the group consisting of: oglio dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers and nucleotides.

A144 (emphasis added).

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STATEMENT OF RELATED CASES

The Appellee is aware of no other appeal from the Board of Patent Appeals and Interferences in connection with the present application before this or any other court.

There is no known related case pending in this or any other court.

**BRIEF FOR APPELLEE DIRECTOR OF THE
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IN RE JOHN NGAI and DAVID LIN

**Appeal from the United States Patent and Trademark Office,
Board of Patent Appeals and Interferences**

STATEMENT OF THE ISSUE

It is well accepted that one cannot obtain a second product patent based on the recitation of a new use for a known product. It is also well established that for printed matter in a claim to be given patentable weight, it must have a functional relationship with the substrate upon which it is printed. The issue in this case is whether an applicant may circumvent these two doctrines by relying on a set of printed instructions reciting a new use of an old product to patentably distinguish his claim from the prior art.

STATEMENT OF THE CASE

This is an appeal from a decision of the Board affirming the final rejection of claim 19 under 35 U.S.C. § 102(b) as anticipated by Stratagene. A11. The examiner allowed method claims 1-18 (A1), and the Board reversed the rejection against dependent claim 20 (A14). Accordingly, this appeal is directed solely to claim 19, which comprises an old product and instructions for the new method.

In an attempt to overcome the anticipation rejection, the Appellants (Ngai) rely on the "instructions" recited in claim 19, which is the only difference between Stratagene and the claim. The Board, however, found that, reading the claim as a whole, the set of instructions describing Ngai's method did not have a functional relationship to anything in the claim. Therefore, the content of the instructions does not patentably distinguish claim 19. This appeal followed.

STATEMENT OF THE FACTS

A. The Claimed Kit: An Old Product With New Instructions

The claimed kit comprises (i) a known product and (ii) written instructions for using that old product. Specifically, Ngai's invention (A133-54) is directed to a new method for normalizing and amplifying polynucleotides. A133. The study of gene sequences provides a wide variety of applications in biotechnology research. A133. In certain cases, however, the amount of starting (or source)

material is often highly limited, making it necessary to “amplify” the targeted message RNA (mRNA) populations. Id. In addition, “normalization” improves the detection of RNA transcripts expressed at low levels. A134, A138. To aid in analyzing gene sequences, Ngai invented a new method for normalizing and amplifying an RNA population.

Method claim 1 is representative of allowed method claims 1-18 and states:

1. A method for normalizing and amplifying an RNA population comprising the steps of:

copying message RNA (mRNA) to form first single-stranded (ss) cDNA;

converting the first ss-cDNA to first double-stranded (ds) cDNA;

linearly amplifying the first ds-cDNA to form first amplified RNA (aRNA);

tagging the 3' end of the first aRNA with a known sequence to form 3'-tagged first aRNA;

copying the 3'-tagged first aRNA to form second ss-cDNA; and

normalizing the mRNA or the first aRNA.

A142.

In addition to Ngai's allowed method claims, Ngai also seeks a claim for an article of manufacture. Claim 19 recites a kit comprising two elements: (i) any of

certain known reagents, e.g., buffers; and (ii) "instructions" describing the steps of method claim 1. Claim 19 states:

19. A kit for normalizing and amplifying an RNA population, said kit comprising instructions describing the method of claim 1 and a premeasured portion of a reagent selected from the group consisting of: oglio dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers and nucleotides.

A144 (emphasis added).

B. The Prior Art Kit: Stratagene

Stratagene (A171-73) teaches a kit comprising a set of instructions describing a method for identifying selectively expressed genes and a 10X buffer, which is a type of reagent. A171; A4.

C. The Board Decision

The Board (A1-14) agreed with the examiner's rejection that Stratagene anticipates claim 19 because it teaches every limitation of the claim. The Board found that Stratagene, like the claimed invention, teaches a kit that includes (i) a buffer reagent along with (ii) instructions for the use of the buffer reagent. A4-5. The Board thus found that the only difference between Stratagene and the claimed kit is the particular content of the printed instructions. A8.

Agreeing with Ngai, the Board recognized that printed matter recited in a claim, in some cases, carries patentable weight. A5. The Board also noted, however, the well-established rule for printed matter that “where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability.” A5 (emphasis added) (quoting In re Gulack, 703 F.2d 1381, 1385 (Fed. Cir. 1983)).

Regarding Ngai’s printed instructions, the Board found that such a functional relationship was lacking, and therefore, the content of those instructions does not distinguish the claimed kit from the teachings of Stratagene. A5. Evaluating claim 19 as a whole, the Board found that instead of a claim limitation, the printed matter instructions were akin to a statement of intended use for an old composition, which does not render the claim patentable. A5-10 (citing, *inter alia*, In re Schreiber 128 F.3d 1473, 1477 (Fed. Cir. 1997), and In re Spada, 911 F.2d 705, 708 (Fed. Cir. 1990)).

Accordingly, since the instructions were not given patentable weight, the Board found that claim 19 essentially claimed nothing more than the old composition. The Board found to hold otherwise would permit the repatenting of old products simply by adding an “instructions” limitation as to the new use. A10-11. The Board determined that such an outcome would be contrary to this Court’s

and its predecessor's bedrock principle that one cannot receive a new product patent based on the recitation of a new use for an existing product.

In a dissenting opinion (A15-26), one Board panel member concluded that the printed information was a structural limitation in the claim and therefore the rejection should be reversed. A17. The dissenting APJ found that the printed instructions meet a version of the functional relationship test required by Gulack, because the instructions, in his view, are functionally related to the other element of the kit, i.e., the reagent. A23. In response, the Board majority noted that the buffer reagent does not change in character into a new type of composition simply by associating it with a label having instructions to show a new use, and therefore, rejected the dissent's view. A8.

SUMMARY OF THE ARGUMENT

The Board properly found that Stratagene anticipates claim 19 because, like the claimed invention, it discloses a kit including (i) a buffer reagent and (ii) a set of instructions. The only difference between claim 19 and the prior art is the content of the instructions.

While certain types of printed matter carry patentable weight, Ngai's instructions do not, because this printed matter is not functionally related to the substrate. Unlike a case where markings on the side of a cup are functionally

related to its substrate such that it transforms a basic cup into a measuring device, Ngai's printed matter simply communicates information to a reader, like a book. Accordingly, in view of the requirements of this Court (and its predecessor), the Board properly determined that the instructions are not a structural limitation and therefore cannot impart patentability to the claim. Thus, when reviewed as a whole, Ngai's claim impermissibly seeks a new product claim on an old product by including the new "instructions." Ngai's invention, however, lies in a new method, not a new product. For that discovery, Ngai's protection under the patent laws is properly defined by his allowed method claims 1-18. To hold otherwise would conflict with a long line of cases consistently rejecting attempts to gain new product claims for old products based on the recitation of new uses.

Finally, Ngai's policy concerns regarding his asserted inability to exclude competitors from exploiting his new method with only his method claims are unfounded, because it is already well-established that a party who sells an old composition along with instructions describing a patented method for using the old composition may be liable for induced infringement of the method claims under 35 U.S.C. § 271(b).

ARGUMENT

A. Standard of Review

Anticipation is a question of fact. Schreiber, 128 F.3d at 1477. Similarly, whether printed matter recited in a claim has a functional relationship with the substrate is a question of fact. See Gulack, 703 F.2d at 1385, 1386 (finding that Gulack's indica is functionally related to the substrate).

This Court upholds USPTO fact findings supported by substantial evidence. 5 U.S.C. § 706(2)(E); In re Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000). Substantial evidence is "such relevant evidence as a reasonable mind might accept to support a conclusion." Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229 (1938). As this Court recently stated, "where two different, inconsistent conclusions may reasonably be drawn from the evidence of record, an agency's decision to favor one conclusion over the other is the epitome of a decision that must be sustained upon review for substantial evidence." In re Jolley, 308 F.3d 1317, 1329 (Fed. Cir. 2002).

B. Stratagene Anticipates Claim 19 Because It Teaches A Kit With A Reagent and Instructions

Ngai does not dispute that the only difference between claim 19 and Stratagene lies in the type of information printed in their instructions. Like the

claimed kit, Stratagene's kit comprises (i) a reagent (10X buffer) and (ii) a set of instructions describing a method for using the reagent. A171; A4. Ngai's sole argument for defeating the rejection is that the specific instruction content of his claim (i.e., the method of claim 1) is a structural limitation that must be given patentable weight. As explained below, that argument fails because the Board properly found that Ngai's instructions lack a functional relationship with the substrate upon which it is printed. Accordingly, Ngai's printed matter is not entitled to patentable weight and does not distinguish claim 19 from the prior art.

C. No Functional Relationship Exists Between The Printed Matter Recited In Claim 19 And Any Substrate

It is well-established that certain categories of printed matter recited in a claim may constitute structural limitations, while other types of printed matter that simply convey information to a reader do not. In the most recent decision addressing "printed matter rejections," this Court reaffirmed the functional relationship test for determining whether printed matter carries patentable weight: "[T]he critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate." In re Lowry, 32 F.3d 1579, 1582 (Fed. Cir. 1994) (emphasis added) (quoting Gulack, 703 F.2d at 1386). However, noting that "printed matter may well constitute structural limitations

upon which patentability can be predicated,” this Court cautioned against a “liberal use” of printed matter rejections. Lowry, 32 F.3d 1579, 1583 (Fed. Cir. 1994) (quoting Gulack, 703 F.2d at 1385 n. 8). Accordingly, when faced with printed matter in a claim, the USPTO may not disregard it, but instead must examine it by determining whether the printed matter is functionally related to the article upon which it is printed, thereby changing the underlying functionality of that article:

Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability. Although the printed matter must be considered, in that situation it may not be entitled to patentable weight.

Gulack, 703 F.2d at 1385 (emphasis added). Accordingly, the dispositive question in this appeal is whether Ngai’s instructions are functionally related to its substrate.

The limited case law applying the functional relationship test underscores the distinction between printed matter that simply conveys information to a reader (as we have here) versus printed matter that interacts with the article upon which it is printed to transform the article into a product with a new and different function. For example, in In re Miller, 418 F.2d 1392 (CCPA 1969), the indicia printed on the side of a cup changed the function of the cup into a specialized measuring

device to prepare fractional recipes. Id. at 1396. In Gulack, 703 F.2d at 1382-83, the invention was directed to a headband having a particular numerical sequence, based on an algorithm, printed on it. The Court found that the number sequence was functionally related to the headband because the circular nature of the headband illustrated the cyclical nature of the particular number sequence. In addition, the number sequence on the headband changed the headband into a device for performing magic tricks based on the algorithm. Id. at 1383.

In Lowry, the Court found that the printed matter doctrine did not apply, because Lowry did not claim “merely the information content of a memory.” Lowry, 32 F.3d at 1583. Instead, the claimed data objects were “electronic structural elements” which imposed a physical organization on the information stored in the memory, thereby providing increased efficiency in computer operation. Id. at 1583-84. Importantly, the Court recognized that Lowry’s data objects were unlike cases in which printed matter did not carry patentable weight, because those cases “dealt with claims defining as the invention certain novel arrangements of printed lines or characters, useful and intelligible only to the

human mind.” Id. at 1583 (quoting In re Bernhart, 417 F.2d 1395, 1399 (CCPA 1969)).¹

In the present case, however, the Board properly found that Ngai’s printed matter lacks the functional relationship required by case law. The Board first correctly recognized, quoting Gulack, that printed matter recited in a claim must be considered, and the USPTO may not simply disregard printed matter without examining it. A5. However, after carefully considering Ngai’s claimed instructions, it found that the printed matter lacked a functional relationship and instead simply described a new use for the old product. A5. Although claim 19 does not specifically indicate where the instructions are printed, whether it is on paper, the side of a container, or somehow on the reagent itself, the combination of the information printed on the substrate does nothing to change the character of the underlying substrate. Ngai’s instructions are not the kind of printed matter contemplated in cases like Lowry, Gulack, and Miller where the printed matter

¹ The printed matter case relied upon by the dissenting member of the Board, In re Royka, 490 F.2d 981 (CCPA 1974), is consistent with the Board’s decision and other printed matter cases. In Royka, the claim covered a self-instruction and testing device having an answer sheet with a correct and incorrect answer, which required the student to erase the wrong answer. Id. Unlike Ngai, Royka did not rely on the meaning of the printed matter to a reader to distinguish the prior art. Instead, the printed matter functionally changed the answer sheet into an interactive learning tool allowing students to remove indicia from the sheet to leave the correct answer. Id. at 984.

changes the underlying functionality of the article upon which it is printed.

Markings on a wooden stick can convert the stick into a ruler, for example, thereby making those printed matter markings a structural limitation. Because no such functional relationship exists for Ngai's instructions, the Board properly declined to give patentable weight to the printed matter.

In the words of Lowry, Ngai's instructions represent nothing more than "novel arrangements of printed lines or characters, useful and intelligible only to the human mind." Id. at 1583. Thus, Ngai seeks to patent the content of the information in the instructions which are intelligible only to the human mind, an outcome precluded by Lowry. Since the instructions do not have a distinct structure that alters or transforms the function of the underlying article upon which it is printed, the printed matter is not a structural limitation which may impart patentability onto the claim. Instead, Ngai merely claims a type of information for communicating intelligence to a reader, like an article or book. As explained above, however, kits comprising "how to use" manuals or labels combined with old products should not be allowed to create a new class of patentable articles of manufacture. Accordingly, the Board properly declined to give patentable weight to the instructions. Therefore, the Board's finding that Stratagene teaches every limitation and anticipates claim 19 is supported by substantial evidence.

D. Simply Adding An “Instructions” Limitation To An Old Product Circumvents The Principle That One Cannot Receive A New Product Claim Based On A New Use For An Old Product

As the Board noted in considering the printed matter recited in claim 19, the instructions simply describe a new use for an old product. Thus, they are akin to “intended use” language which cannot impart patentability to a product claim. “It is well settled that the recitation of a new intended use for an old product does not make the claim to that old product patentable.” In re Schreiber, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (quoting, *inter alia*, In re Spada, 911 F.2d 705, 708 (Fed. Cir. 1990) (“[t]he discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, cannot impart patentability to claims to the known composition.”)).² Accordingly, claim 19 is precluded by Schreiber and Spada.

Ngai argues that he is not seeking to repatent an old composition, but is instead claiming a new combination, the kit. Br. at 6. The inclusion of a statement of use on a label, however, does not give that statement patentable significance that it would not otherwise have. The claimed kit is thus limited by

² Contrary to Ngai’s assertions in his opening brief (Br. at 7), the Board correctly recognized, relying on In re Stencel, 828 F.2d 751, 753 (Fed. Cir. 1987), that statements of intended use may appear in a claim in places other than the preamble. A8-9.

only one element, the old composition. Thus, as the Board correctly recognized (A11), the claimed kit ultimately is an attempt to repatent an old composition, via claim drafting, based on a description of a new intended use. Allowing such a claim would circumvent the law preventing claims for old compositions based on statements describing a new use. See, e.g., Schreiber, 128 F.3d at 1477, Spada, 911 F.2d at 708; In re Pearson, 494 F.2d 1399, 1403 (CCPA 1974); In re Zierden, 411 F.2d 1325, 1328 (CCPA 1969) (“A mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable.”); In re Hack, 245 F.2d 246, 248 (CCPA 1957) (“As a matter of claim drafting, therefore, the discoverer of a new use must protect his discovery by means of process or method claims and not product claims.”).

Moreover, to hold otherwise would appear to produce opposite results in several of this Court’s cases, if an additional instructions limitation was added to those claims. For example, in Schreiber, the court affirmed the anticipation rejection of applicant’s claims for a funnel for dispensing popcorn over a reference disclosing a funnel for dispensing oil. Schreiber, 128 F.3d at 1475-78. A reversal of the rejection in this case would likewise permit the applicant in Schreiber to gain a patent by simply printing his recited, intended use on a label and attaching it to his funnel.

Similarly, in Pearson, the court affirmed the rejection of applicant's claims for a calcium-containing compound of reduced particle size for reducing pops and unsound kernels in a peanut crop. Pearson, 494 F.2d at 1400-03. Although the applicant admitted that the compound and particle size were known, he asserted that his particular use for the compound patentably distinguished his claim. The court disagreed, determining that the recitation of a new use in a claim for an old product fails to differentiate the claim from the prior art:

It seems quite clear to us that one of the compositions admitted to be old by the appellant would not undergo a metamorphosis to a new composition by labeling its container to show that it is a composition suitable for treating peanuts to avoid the formation of pops and unsound kernels.

Id. at 1403. Accordingly, permitting Ngai to receive his product claim with an instruction label appears to directly conflict with the above-quoted reasoning from Pearson, or, in the alternative, require a different result in Pearson.

E. Ngai's Remaining Arguments Do Not Warrant Giving Him A Product Claim On A Known Product

Ngai contends that his printed matter should be considered a limitation because, in his view, the USPTO has issued several other patents that include printed instruction limitations in the claims. Br. at 5-6. The Board correctly rejected this argument, since it is well settled that whether similar claims have

been allowed in other cases is immaterial. A7 (citing In re Giolito, 530 F.2d 397, 400 (CCPA 1976)). See also In re Wertheim, 541 F.2d 257, 264 (CCPA 1976); In re Gyurik, 596 F.2d 1012, 1018 n.15 (CCPA 1979) ("this court does not consider allowed claims in other applications or patents").³

Finally, Ngai makes a policy argument, contending that he needs an article of manufacture claim to protect his "innovative and commercially valuable method" from being exploited by competitors selling the kit. Br. at 7-8. In Ngai's case, however, that concern is unfounded because any such competitor selling a kit of a reagent with an instruction sheet describing Ngai's method may be liable for infringement of Ngai's method claims under 35 U.S.C. § 271(b). The law is clear that a party selling products capable of infringing a patented method, while also providing instructions or advertising with directions as to the infringing use, may be liable for induced infringement. See Chiuminatta Concrete Concepts v. Cardinal Indus., 145 F.3d 1303, 1311-12 (Fed. Cir. 1998) (finding accused infringer actively induced infringement of a method claim that required cutting concrete at a specific stage of hardening with advertisements encouraging use of

³ In addition, the dissenting APJ's reliance on In re Ochiai, 71 F.3d 1565 (Fed. Cir. 1995) (see A17-18) is misplaced because the new compound recited in Ochiai's method claim was a structural limitation, unlike the printed method instructions recited in Ngai's claim, as already explained above.

infringer's rotary saw at a stage that fell within the claim); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1272 (Fed. Cir. 1986) (finding patentee met its burden of showing infringement under section 271(b) with evidence of extensive cube puzzle sales along with dissemination of an instruction sheet teaching the claimed method of solving the cube puzzle); see also Hilgraeve Corp. v. Symantec Corp., 265 F.3d 1336, 1343 (Fed. Cir. 2001) (“[T]he sale of a device may induce infringement of a method claim, even if the accused device is capable of non-infringing modes of operation in unusual circumstances.”).

Accordingly, there is no policy concern warranting the issuance of product claims to known products simply by also claiming instruction sheets describing a new use. In fact, as a matter of policy, allowing claim 19 would significantly alter patent practice by allowing information to be considered a product element deserving patentable weight. As already indicated in Lowry, it is inappropriate to treat information as a product element in a claim. See Lowry, 32 F.3d at 1583-84; see also Bayer AG v. Housey Pharmaceuticals, Inc., 340 F.3d 1367 (Fed. Cir. 2003) (information resulting from a patented process held not to be a product under 35 USC 271(g)). At bottom, Ngai invented a new method to use an old product (claims 1-18), and that is what he is entitled to for patent protection, nothing less, but nothing more.

CONCLUSION

Substantial evidence supports the Board's finding that claim 19 is anticipated because Stratagene discloses every claim limitation. This Court should therefore affirm the Board's decision.

Respectfully submitted,


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December 10, 2003

CERTIFICATE OF SERVICE

I hereby certify that on December 10, 2003, I caused two copies of the foregoing BRIEF FOR APPELLEE DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE to be transmitted by overnight delivery to:

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A handwritten signature in black ink, appearing to read 'R. T. Chen', written over a horizontal line.

RAYMOND T. CHEN
Associate Solicitor